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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,960	10/19/2001	Maria A. Glucksmann	381552004400	1608
7590	07/01/2004			
INTELLECTUAL PROPERTY GROUP MILLENNIUM PHARMACEUTICALS INC. 75 SIDNEY STREET CAMBRIDGE, MA 02139			EXAMINER SAIDHA, TEKCHAND	
			ART UNIT 1652	PAPER NUMBER

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

10/080,960

**Applicant(s)**

GLUCKSMANN ET AL.

**Examiner**

Tekchand Saidha

**Art Unit**

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Election/Restrictions***

- I. Restriction to one of the following inventions is required under 35 U.S.C. 121:
1. Claims 1-3 & 6 (all in-part), drawn to nucleic acid sequence SEQ ID NO: 1 (cDNA) & SEQ ID NO: 3 (coding), designated 80090, host cell and method of making polypeptide of SEQ ID NO: 2, classified in class 435, subclass 69.1.
  2. Claims 1-3 & 6 (all in-part), drawn to nucleic acid sequence SEQ ID NO: 4 (cDNA) & SEQ ID NO: 6 (coding), designated 52874, host cell and method of making polypeptide of SEQ ID NO: 5, classified in class 435, subclass 69.1.
  3. Claims 1-3 & 6 (all in-part), drawn to nucleic acid sequence SEQ ID NO: 47(cDNA) & SEQ ID NO: 9 (coding), designated 52880, host cell and method of making polypeptide of SEQ ID NO: 8, classified in class 435, subclass 69.1.
  4. Claims 1-3 & 6 (all in-part), drawn to nucleic acid sequence SEQ ID NO: 10 (cDNA) & SEQ ID NO: 12 (coding), designated 63497, host cell and method of making polypeptide of SEQ ID NO: 11, classified in class 435, subclass 69.1.
  5. Claims 1-3 & 6 (all in-part), drawn to nucleic acid sequence SEQ ID NO: 13 (cDNA) & SEQ ID NO: 15 (coding), designated 33425, host cell and method of making polypeptide of SEQ ID NO: 14, classified in class 435, subclass 69.1.

6. Claim 4 (in-part), drawn to polypeptide of SEQ ID NO: 2, classified in class 530, subclass 350.
7. Claim 4 (in-part), drawn to polypeptide of SEQ ID NO: 5, classified in class 530, subclass 350.
8. Claim 4 (in-part), drawn to polypeptide of SEQ ID NO: 8, classified in class 530, subclass 350.
9. Claim 4 (in-part), drawn to polypeptide of SEQ ID NO: 11, classified in class 530, subclass 350.
10. Claim 4 (in-part), drawn to polypeptide of SEQ ID NO: 14, classified in class 530, subclass 350.
11. Claim 5 (in-part), drawn to antibody to the polypeptide of SEQ ID NO: 2, classified in class 530, subclass 387.1.
12. Claim 5 (in-part), drawn to antibody to the polypeptide of SEQ ID NO: 5, classified in class 530, subclass 387.1.
13. Claim 5 (in-part), drawn to antibody to the polypeptide of SEQ ID NO: 8, classified in class 530, subclass 387.1.
14. Claim 5 (in-part), drawn to antibody to the polypeptide of SEQ ID NO: 11, classified in class 530, subclass 387.1.
15. Claim 5 (in-part), drawn to antibody to the polypeptide of SEQ ID NO: 14, classified in class 530, subclass 387.1.
16. Claims 7-8, 11-12, 14-15 (all in-part), drawn to a method of detecting nucleic acid (hybridization) of SEQ ID Nos. 1 & 3.

17. Claims 7-8, 11-12, 14-15 (all in-part), drawn to a method of detecting nucleic acid (hybridization) of SEQ ID Nos. 4 & 6.
18. Claims 7-8, 11-12, 14-15 (all in-part), drawn to a method of detecting nucleic acid (hybridization) of SEQ ID Nos. 7 & 9.
19. Claims 7-8, 11-12, 14-15 (all in-part), drawn to a method of detecting nucleic acid (hybridization) of SEQ ID Nos. 10 & 12.
20. Claims 7-8, 11-12, 14-15 (all in-part), drawn to a method of detecting nucleic acid (hybridization) of SEQ ID Nos. 13 & 15.
21. Claims 7-8, 13 & 16 (all in-part), drawn to a method of detecting polypeptide of SEQ ID NO: 2.
22. Claims 7-8, 13 & 16 (all in-part), drawn to a method of detecting polypeptide of SEQ ID NO: 5.
23. Claims 7-8, 13 & 16 (all in-part), drawn to a method of detecting polypeptide of SEQ ID NO: 8.
24. Claims 7-8, 13 & 16 (all in-part), drawn to a method of detecting polypeptide of SEQ ID NO: 11.
25. Claims 7-8, 13 & 16 (all in-part), drawn to a method of detecting polypeptide of SEQ ID NO: 14.
26. Claims 9-10 (all in-part), drawn to a method of identifying a compound that binds to polypeptide of SEQ ID NO: 2.
27. Claims 9-10 (all in-part), drawn to a method of identifying a compound that binds to polypeptide of SEQ ID NO: 5.

28. Claims 9-10 (all in-part), drawn to a method of identifying a compound that binds to polypeptide of SEQ ID NO: 8.
29. Claims 9-10 (all in-part), drawn to a method of identifying a compound that binds to polypeptide of SEQ ID NO: 11.
30. Claims 9-10 (all in-part), drawn to a method of identifying a compound that binds to polypeptide of SEQ ID NO: 14.
31. Claim 17 (in-part), drawn to a method of identifying a compound capable of treating a disorder characterized nucleic acid expression of SEQ ID Nos. 1 & 3.
32. Claim 17 (in-part), drawn to a method of identifying a compound capable of treating a disorder characterized nucleic acid expression of SEQ ID Nos. 4 & 6.
33. Claim 17 (in-part), drawn to a method of identifying a compound capable of treating a disorder characterized nucleic acid expression of SEQ ID Nos. 7 & 9.
34. Claim 17 (in-part), drawn to a method of identifying a compound capable of treating a disorder characterized nucleic acid expression of SEQ ID Nos. 10 & 12.
35. Claim 17 (in-part), drawn to a method of identifying a compound capable of treating a disorder characterized nucleic acid expression of SEQ ID Nos. 13 & 15.

36. Claims 17 & 18-24 (all in-part), drawn to a method of identifying a compound capable of treating a disorder characterized by the polypeptide activity of SEQ ID NO: 2.
37. Claims 17 & 18-24 (all in-part), drawn to a method of identifying a compound capable of treating a disorder characterized by the polypeptide activity of SEQ ID NO: 5.
38. Claims 17 & 18-24 (all in-part), drawn to a method of identifying a compound capable of treating a disorder characterized by the polypeptide activity of SEQ ID NO: 8.
39. Claims 17 & 18-24 (all in-part), drawn to a method of identifying a compound capable of treating a disorder characterized by the polypeptide activity of SEQ ID NO: 11.
40. Claims 17 & 18-24 (all in-part), drawn to a method of identifying a compound capable of treating a disorder characterized by the polypeptide activity of SEQ ID NO: 14.

II. The inventions are distinct, each from the other because of the following reasons:

The DNA of each of the Inventions (or Groups) 1-5 is related to the protein of Inventions 6-10 by virtue of the fact that the DNA codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source.

Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays. Each of the DNA sequences of Inventions 1-5 are structurally distinct from each other, therefore require a separate sequence search. Similarly, each of the polypeptide sequences of Inventions 6-10 are structurally distinct from each other, therefore require a separate sequence search. This additional search for each of the distinct DNA or protein molecule will be undue burden on the examiner.

Each of the Inventions 1-5 and 11-15 are patentably distinct from each other. The nucleic acids, vectors, cells, and methods of Groups 1-5 and the antibodies and methods of Group 11-15 do not require each other for their practice; have separate utilities, such as use of nucleic acids, vectors, cells, and methods to recombinantly produce protein versus use of the antibodies to detect proteins; are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

Each of the Inventions 6-10 and 11-15 are distinct because protein and antibody are chemically and biologically distinct molecules. Antibody and protein have fundamentally different molecular structure, each with its own set of functionality. Antibodies, for example, are formed in the B-cells and are useful for binding to particular residues. Proteins do not function to bind in the particular immunological way that antibodies do, and therefore have different specificities for different substrates, and do not purport to have the kinds of specific activity that antibodies have.



Each of the Inventions 1-5 and 16-20 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case the specific & distinct polypeptide encoding nucleic acid molecules, as claimed in each of the Groups 1-5, can be used in a materially different process other than the methods to detect transcripts, claimed in Groups 16-20, such as use of the nucleic acids in a method to produce recombinant distinct proteins of sequences of SEQ ID Nos. 2, 5, 8, 11 or 14.

Each of the Inventions 6-10 and 21-25 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case the specific & distinct polypeptide molecules, as claimed in each of the Groups 6-10, can be used in a materially different process other than the methods to detect polypeptide, claimed in Groups 21-25, such as use of the polypeptide in the identification of modulators (inhibitors or activators).

Each of the Inventions of groups 26-40, though employ the distinct polypeptide or DNA, are similarly distinct because the (1) the process for using the product as claimed

can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product.

III. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

IV. A telephone call was not made to request an oral election to the above restriction requirement.

V. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

VI. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

VII. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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